APPLICATION FOR
UNITED STATES LETTERS PATENT

For:

ARTIFICIAL INTERVERTEBRAL DISC

By:

Nabil L. Muhanna and Lance M. Middleton

FIELD OF THE INVENTION

The present invention generally relates to an apparatus for the treatment of spinal disorders and, in particular, an artificial intervertebral disc, an implant that replaces a diseased or damaged intervertebral disc.

BACKGROUND OF THE INVENTION

[0001] There are many painful disorders of the spine, many relating, at least in part, to diseased or damaged intervertebral discs. Disorders include Degenerative Disc Disease, generally an age related disorder where the intervertebral disc gradually loses its water content, resiliency, and height. With a loss in intervertebral disc height and associated loss of normal spacing between vertebrae, motion of the vertebrae can place pressure on the spinal cord or exiting nerve roots. The intervertebral disc itself can also be a source of pain. Spinal disorders, commonly referred to as disc herniation and bulging disc, place painful pressure on the spinal cord and exiting nerve roots. Abnormal bone growth, called osteophytes, can place pressure on nerves or the spinal cord. Often, a surgeon must at least partially remove an intervertebral disc to access and remove an osteophyte.

[0002] A surgical approach to treating chronic spinal disorders relates to bony fusion of two adjacent vertebrae in a treatment called spine fusion. Following the achievement of appropriate spacing and alignment of the vertebral bodies, bone graft material and stabilization provide an environment for spine fusion. Implant systems, to include plate and rod systems and interbody devices, such as, interbody spacers and fusion cages can be used to support the spine during fusion. Concerns persist regarding spinal fusion treatment stemming from modest clinical success rates and the creation of rigid regions along an otherwise flexible spine.

[0003] Artificial intervertebral discs, or simply artificial discs, are an alternative to spinal fusion and represent an emerging technology. These spinal implants are designed to restore or maintain the appropriate alignment and spacing of adjacent vertebral bodies. In addition, an artificial disc is also designed for kinematic behavior similar to a healthy natural disc. Known artificial disc concepts use numerous means for providing motion and stiffness similar to a natural healthy disc, to include the adaptation of elastomers, mechanical springs, and articulating surfaces.

[0004] Prior art artificial discs often use articulating surfaces to create a joint between adjacent vertebrae. Disc implants using articulating surfaces rely on methodology and proven technology used in total joint arthroplasty of the hip, knee, and shoulder. Numerous prior art artificial discs resemble artificial hip and artificial knee joints. Numerous known artificial disc devices resemble variations of a ball-and-socket. Kuntz, in US Patent 4,349,921 (September 21, 1982) discloses an artificial disc, with two components that articulate by means of a projection on one component pivotally engaging a depression on the second component. An artificial disc resembling an artificial knee joint has also been suggested. Shelokov, in US Patent 6,039,763 (March 21, 2000) discloses an artificial spinal disc, similar in configuration to an artificial knee joint.

[0005] Heggeness et. al., in US Patent 5,514,180 (May 1996) categorizes the shape or contours of vertebral endplates into five groups: "ramp", "saddle", "irregular", "bowl", and "hump". Heggeness et. al., teaches the importance of endplate shape relating to fit and load distribution of a prosthetic devices within intervertebral disc spaces, but

Heggeness et. al. does not discuss endplate shape relating to articulating surfaces or spinal kinematics.

[0006] Spine kinematics and anatomical shapes vary by region of the spine (cervical, thoracic, and lumbar), and a need exists for artificial discs addressing specific regions of the spine, especially the unique geometry and kinematics of the cervical spine.

SUMMARY OF THE INVENTION

[0007] For the middle and lower regions of the cervical spine, the artificial disc of the present invention adapts an articulating surface with a concave-convex shape, also called a saddle shape. The artificial disc of the present invention is intended to fit substantially within the intervertebral space bound by adjacent vertebral bodies. A bone anchor for fixation of an artificial disc to vertebra is also disclosed.

[0008] A first embodiment of the artificial disc of the present invention for the cervical spine includes a disc body having an articulating concave-convex surface secured to a base plate, which may incorporate a bone anchor. A second embodiment of the artificial disc of the present invention is comprised of an articulating concave-convex surface, bone anchor, and a disc body slidably attached to a base plate to permit additional motion. A third embodiment of the artificial disc of the present invention includes an upper disc body and a lower disc body cooperatively forming a saddle-joint. The upper disc body and lower disc body of the third embodiment are securely anchored to vertebral bodies using bone anchors. Further embodiments of the artificial disc of the present invention include an upper disc body and a lower disc body cooperatively forming a saddle-joint, and bone anchors adapted with a tension element to provide additional stability.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a frontal view of a cervical spine motion segment comprised of two vertebrae and an intervertebral disc.

FIG. 2A shows a cervical vertebra in a perspective view of the superior endplate.

FIG. 2B shows an alternate perspective view of the cervical vertebra shown in FIG. 1A to emphasize the inferior endplate.

FIG. 3 shows a first preferred embodiment artificial disc of the present invention for the cervical spine with an articulating concave-convex surface.

FIG. 4A, FIG. 4B, and FIG. 4C show the artificial disc depicted in FIG. 3 in orthogonal views to include a front view, side view, and top view, respectively.

FIG. 5 shows the artificial disc depicted in FIG. 3 in an exploded view to include adjacent vertebrae of the cervical spine.

FIG. 6 shows a midsagittal sectional view of the first preferred embodiment artificial disc of the present invention depicted in FIG. 3 between adjacent cervical vertebrae.

FIG. 7 shows a midsagittal sectional view of a first preferred embodiment artificial disc of the present invention depicted in FIG. 3 with a schematic of Instantaneous-Axis-of-Rotation (IAR) of a superior vertebra in flexion.

FIG. 8 shows a second preferred embodiment artificial disc of the present invention with a disc body slidably attached to a base plate to permit rotational and translational sliding.

FIG. 9 shows a third preferred embodiment artificial disc of the present invention to include an upper disc body and a lower disc body cooperatively forming a saddle-joint with concave-convex surfaces.

FIG. 10 shows a fourth preferred embodiment artificial disc of the present invention to include an upper disc body and a lower disc body cooperatively forming a saddle-joint with concave-convex surfaces and a tension cable.

FIG. 11 shows a fifth preferred embodiment artificial disc of the present invention to include an upper disc body and a lower disc body cooperatively forming a saddle-joint with concave-convex surfaces and a flexible plate.

FIG. 12 shows a sixth preferred embodiment artificial disc of the present invention with an upper articulating concave-convex surface and a lower articulating surface.

DETAILED DESCRIPTION

[0009] Consistent with common medical nomenclature, superior is nearer the head in relation to a specific reference point, whereas, inferior is nearer the feet in relation to a specific reference point. Anterior is forward in relation to a specific reference point and posterior is rearward in relation to a specific reference point. The midsagittal plane is an imaginary plane dividing the body into a right side and left side. A frontal plane is any imaginary vertical plane orthogonal to the midsagittal plane.

[0010] FIG.1 shows a cervical spinal motion segment **1** characteristic of the middle and lower cervical spine comprised of a superior vertebra **10**, an intervertebral disc **7**, and an inferior vertebra **10'**. Superior vertebra **10** is divided into two regions to include superior vertebral body **11** and superior posterior elements **17**. Similarly, inferior vertebra **10'** is

divided into two regions to include inferior vertebral body **11'** and inferior posterior elements **17'**. Although separated by the intervertebral disc **7** to permit motion, the superior vertebral body **11** and the inferior vertebral body **11'** are anatomically interlocking due to the reciprocal reception of the generally saddle-shaped inferior endplate **23** of the superior vertebral body **11** with the superior endplate **13'** of inferior vertebral body **11'**. Although the spinal motion segments are not a synovial joint, the most closely related synovial joint to the middle and lower cervical spine motion segments is the carpometacarpal joint of the thumb, which is formed by articulating surfaces in the form of a saddle-joint. In contrast, the vertebral bodies of other regions of the spine (thoracic and lumbar) are not anatomically interlocking.

[0011] FIG. 2A and FIG. 2B show cervical vertebra **10** of FIG. 1 viewed at different perspectives to highlight superior endplate **13** and inferior endplate **23**, respectively. Consistent with established medical nomenclature, cervical vertebra **10** includes vertebral body **11**, and the bony structures attached to vertebral body **11** are posterior elements **17**. The superior endplate **13** is generally concave, or at least partially concave, as indicated by the superior frontal surface line **14**. The superior midsagittal surface line **15** is substantially straight but may be slightly concave or convex, or at least partially concave or convex. The inferior concave-convex endplate **23** is substantially convex in the medial-lateral direction and substantially concave in the anterior/posterior direction to form a saddle surface, as indicated by inferior convex surface line **24** and inferior concave surface line **25**.

[0012] Primarily addressing the middle and lower cervical spine, the present invention uses a generally concave-convex articulating surface. As will become apparent in

subsequent discussion, a concave-convex articulating surface is an essential element of the present invention, providing anatomical and biomechanical advantages. Referring now to FIG. 3, a first preferred embodiment, artificial disc **100**, is comprised of a disc body **130**, base plate **138**, and bone anchor **150**. Concave-convex articulating surface **133** is further revealed by considering two example reference lines formed from convenient planer reference planes, concave surface line **134** and midsagittal convex surface line **135**. The curvature of concave-convex articulating surface **133** may be formed of simple radii or variable radii, and may be further expressed mathematically, at least in part, as a hyperbolic paraboloid, saddle-surface, or surface with negative curvature As will become apparent in subsequent discussion, a concave-convex articulating surface is an essential element of the present invention, providing anatomical and biomechanical advantages. Disc body **130** and base plate **138** are shown as separate components, although manufacture as a single component is also contemplated. Disc body **130** has a height appropriate for spacing of the vertebral bodies and may be of various shapes and sizes in order to substantially fill the surgically prepared space between vertebral bodies. Base plate **138** may have planer surfaces and uniform thickness, as shown in FIG. 3, although variable thickness and curved surfaces are also contemplated. Bone anchor **150** and base plate **138** are adapted for fixation to bone. Bone anchor **150** is comprised of vertical anchor web **152**, anchor body **154**, and anchor hole **156**. As shown in FIG. 3, vertical anchor web **152** has a vertical height greater than width. In addition, vertical anchor web **152** may take other various forms, to include, but not be limited to, a web with variable thickness. Anchor body **154** is a protuberance with a width substantially greater than the thickness of vertical anchor web **152**. As shown in

FIG. 3, anchor body **154** is cylindrical, but other shapes are also contemplated, to include, but not limited to, a box shape. A use of anchor hole **156** is to releasably attach a surgical instrument during insertion of artificial disc **100**. FIG. 4A, FIG. 4B, and FIG. 4C show artificial disc **100** in orthogonal views to include a front view, side view, and top view, respectively

[0013] FIG. 5 shows the first preferred embodiment artificial disc **100** of the present invention depicted in FIG. 3 in an exploded perspective view between superior cervical vertebra **110** and inferior cervical vertebra **110'**. Inferior vertebral body **111'** includes a surgically created vertebral body key-hole **128'** intended to receive bone anchor **150**. Bone anchor **150** provides secure interlocking fixation with inferior vertebral body **111'** and requires a minimal amount of bone removal.

[0014] FIG. 6 shows a midsagittal sectional view of the first preferred embodiment artificial disc **100** depicted in FIG. 3 between superior cervical vertebra **110** and inferior cervical vertebra **110'**. Superior vertebra **110** is comprised of superior vertebral body **111** and superior posterior elements **117**. Similarly, inferior vertebra **110'** is divided into two regions to include inferior vertebral body **111'** and inferior posterior elements **117'**. Concave-convex articulating surface **133** is intended to slide with respect to inferior concave-convex endplate **123** provided the cartilaginous inferior concave-convex endplate **123** remains substantially intact following treatment of the patient's pathology. The contour of concave-convex articulating surface **133** is substantially similar to the contour of inferior concave-convex endplate **123**, although some mismatch and variability is expected. It is expected that a patient's endplate can modify and generally adapt to the shape of an implant during healing. Bone anchor **150** is positioned within

vertebral body key-hole **128'**. Base plate **138** may have additional features for bony in-growth into inferior vertebral body **111'** through the use of established porous materials or surface treatments. The anatomically aligned shape of artificial disc **100** results in a near complete fill of the intervertebral disc space; the resulting construct is substantially free of large voids that are potentially susceptible to eventual tissue encroachment. Significant tissue encroachment into an artificial disc could potentially interfere with movement of an artificial disc. Finally, the anatomically aligned shape of artificial disc **100** is intended to fit within the intervertebral disc space with minimal bone removal and endplate preparation during surgery, reducing surgical time and preserving otherwise healthy tissue.

[0015] The anatomically aligned shape of the present invention also has biomechanical benefits associated with natural kinematics of the spine. To assist with the analysis of spine kinematics, Panjabi and White established the Instantaneous-Axis-of-Rotation (IAR) for planer motion analysis of vertebrae. Planar motion of vertebrae is fully described by the position of the IAR and the angle of rotation about the IAR. The IAR is an instantaneous measure and therefore may shift within a region through a range-of-motion, such as, but not limited to, flexion/extension range-of-motion. The present inventors have discovered a relation between the shape of a vertebra's inferior endplate and the natural motion of the same vertebra.

[0016] Flexion/extension is the most commonly considered degree-of-freedom when evaluating cervical spine kinematics. FIG. 7 shows the first preferred embodiment, artificial disc **100** depicted in FIG. 3, in a midsagittal sectional view between superior vertebra **110** and inferior vertebra **110'**. Superior vertebra **110** is shown in a neutral

position with locator point **A1** and locator point **B1** and in a flexed position with locator point **A2** and locator point **B2**. Locator points may be any two unique points on a vertebra, and convenient anatomical landmarks are often used for these reference points. The selected frame of reference is inferior vertebra **110'**, so the instantaneous-axis-of-rotation **IAR** is of superior vertebra **110** with respect to inferior vertebrae **110'**. Continuing to refer to FIG. 7, instantaneous-axis-of-rotation **IAR** is established by determining the intersection of line **LA** and line **LB**, where line **LA** and line **LB** are bisected normal lines of translation vector **A1A2** and translation vector **B1B2**, respectively. Concave-convex articulating surface **133** has been adapted to have a substantially similar shape to inferior concave-convex endplate **123**. Continuing to refer to FIG. 7, inferior concave-convex endplate **123** sliding with respect to concave-convex articulating surface **133** establishes the motion in flexion. The general region of Instantaneous-Axis-of-Rotation **IAR** is within the posterior region of inferior vertebral body **111'**. Concerning the middle and lower cervical spine, the Instantaneous-Axis-of-Rotation **IAR** in flexion/extension of artificial disc **100**, shown in FIG. 7, is consistent with recent scientific research demonstrating the IAR of a superior vertebra in flexion/extension generally lay within a posterior region of an inferior vertebral body (DiAngelo et. al., proceedings of Cervical Spine Research Society Meeting 2000). Further, the mathematical equations defining the shape of concave-convex articulating surface **133**, generally in the form of a hyperbolic paraboloid, can be developed to substantially replicate the complex natural motions of the spine, to include, but not limited to, flexion/extension, lateral bending, and torsional motion.

[0017] Within the scope of the present invention, multiple components may be allowed to articulate to address multiple degrees-of-freedom associated with spinal motion, to include, but not limited to, torsional and translational degrees-of-freedom. Accordingly, FIG. 8 shows a second preferred embodiment of the present invention, artificial disc **200** in an exploded perspective view. Artificial disc **200** is comprised of a disc body **230**, concave-convex articulating surface **233**, base plate **238**, and bone anchor **250**. Bone anchor **250** is comprised of vertical web **252** and anchor body **254**. Base plate protrusion **240** inserts into disc body socket **236**, while disc body articulating surface **237** and base plate articulating surface **239** allow sliding rotation of disc body **230** about axis X-X **245**. Alternately, disc body socket **236** may take various shapes and sizes relative to base plate protrusion **240** to allow planer translation between disc body **230** and base plate **238**. For example, disc body socket **236** may take the form of an elongated slot. Although, disc body articulating surface **237** and base plate articulating surface **239** are shown as planer surfaces, curved surfaces are also contemplated. A cylindrical shape for base plate protrusion **240** is shown in FIG. 8, however, other shapes are also envisioned within the scope of the present invention.

[0018] For a number of reasons, to include anatomical variation, the inferior endplate of a superior vertebra may not be suitable as an articulating surface. During treatment of a cervical spine disorders, endplates are often partially or completely removed in order to access and remove offending soft tissue (e.g., extruded disc nucleus) or offending hard tissue (e.g., posterior bone spurs). A total joint artificial disc is often warranted. Accordingly, FIG. 9 shows a third preferred embodiment of the present invention, artificial disc **300**, comprised of lower disc body **330** and upper disc body **370**. Lower

disc body **330**, attached to lower base plate **338,** has a lower body concave-convex articulating surface **333**. Lower bone anchor **350** is comprised of lower vertical web **352** and lower anchor body **354**. Upper disc body **370** is comprised of upper base plate **378,** upper body concave-convex articulating surface **373**, and upper bone anchor **380**. Upper bone anchor **380** is comprised of upper vertical web **382** and upper anchor body **384**. Lower anchor hole **356** and upper anchor hole **386** can be used to releasably attach a surgical instrument during implantation of artificial disc **300**. Lower body concave-convex articulating surface **333** is further defined by concave surface line **334** and midsagittal convex surface line **335**. Lower base plate **338** and lower bone anchor **350** are adapted for fixation to an inferior vertebra. Similarly, upper bone anchor **380**, comprised of upper vertical anchor web **382** and upper anchor body **384** are adapted for body fixation to a vertebra. The reciprocal reception of lower body concave-convex articulating surface **333** with upper body concave-convex articulating surface **373** forms a saddle-joint. The complement of lower body concave surface line **334** is upper body convex surface line **374**, and the complement of lower body convex surface line **335** is upper body concave surface line **375**. Surface contours of lower body concave-convex articulating surface **333** and upper body concave-convex articulating surface **373** may be dimensionally matched. Or, surface contours of lower body concave-convex articulating surface **333** and upper body concave-convex articulating surface **373** may be cooperatively aligned, but dimensionally mismatched to give the saddle-joint additional freedom ("toggle") or to establish selected regions of surface contact within manufacturing tolerances. A "gentle braking" occurs in torsion between the lower disc body **330** and the upper disc body **370** as the lower body concave-convex articulating

surface **333** and upper body concave-convex articulating surface **373** interact during a torsional motion away from a neutral position, reflecting a more natural resistance to torsional loading. In addition, the surface geometry defining the articulating interaction of lower body concave-convex articulating surface **333** and upper body concave-convex articulating surface **373** may be developed to substantially replicate the complex natural motions of the spine, to include, but not limited to, flexion/extension, lateral bending, and torsional motion.

[0019] Using an anterior approach to the cervical spine, the anterior longitudinal ligament is at least partially resected with associated loss of stability, especially in extension. An artificial disc with a tension element provides stability during extension. Referring now to FIG. 10, a fourth preferred embodiment is shown, artificial disc **400**, comprised of lower disc body **430** and upper disc body **470**. Lower disc body **430** is joined to lower base plate **438**. Lower disc body **430** is also comprised of a lower body concave-convex articulating surface **433**. Lower bone anchor **450**, comprised of lower vertical web **452** and lower anchor body **454**, is adapted for fixation to bone. Upper disc body **470** comprised of upper base plate **478**, upper body concave-convex articulating surface **473** and upper bone anchor **480**. Upper bone anchor **480** is comprised of upper vertical web **482** and upper anchor body **484**. One use of lower anchor hole **456** and upper anchor hole **486** is to releasably attach a surgical instrument during insertion of artificial disc **400**. A saddle-joint is formed by the reciprocal reception of lower body concave-convex articulating surface **433** with upper body concave-convex articulating surface **473**. Tension cable **490**, to include cable knot **491**, is secured through the lower

anchor eyelet **458** and the upper anchor eyelet **488**. Tension cable **490** provides additional stability, restricting motion, especially during extreme extension.

[0020] FIG. 11 shows a fifth preferred embodiment, artificial disc **500**, comprised of lower disc body **530** and upper disc body **570**. Lower disc body **530** includes lower body concave-convex articulating surface **533**. Lower disc body **530** is attached to lower base plate **538**. Lower bone anchor **550**, adapted for interlocking connection to bone, is comprised of lower vertical web **552** and lower anchor body **554**. Upper disc body **570** is comprised of upper base plate **578** and upper body concave-convex articulating surface **573**. Upper bone anchor **580** is comprised of upper vertical web **582** and upper anchor body **584**. The reciprocal reception of lower body concave-convex articulating surface **533** with upper body concave-convex articulating surface **573** forms a saddle-joint. Flexible plate **590** is secured to lower anchor body **550** and upper anchor body **580** by lower fastener **594'** and upper fastener **594**, respectively. Flexible plate **590** is intended to provide greater stability in extension. To allow specified range-of-motion in extension and flexion where flexible plate **590** is not substantially under load, lower fastener **594'** and upper fastener **594** are intended to slide with respect to lower plate slot **592'** and upper plate slot **592**, respectively.

[0021] Within the scope of the current invention, an artificial disc may have an upper articulating surface and a lower articulating surface for sliding interaction with vertebral bodies. FIG. 12 shows a sixth preferred embodiment, artificial disc **600**, comprised of disc body **630**, upper articulating concave-convex surface **633** and lower articulating surface **673**. Curvature of upper articulating concave-convex surface **633** is further defined by concave surface line **634** and midsagittal convex surface line **635**. Lower

surface line **674** is at least generally convex and lower midsagittal plane surface line **675** is generally straight, but may also have curvature.

[0022] The present invention, to include, but not limited to the aforementioned embodiments, can be constructed of established orthopaedic materials. Established wear resistant materials for components with articulating surfaces include metals (e.g., stainless-steel, cobalt-chrome, and titanium), plastics (e.g., Ultra-High-Molecular-Weight-Polyethylene), and ceramics (e.g., alumina and zironia). Non-articulating features of an artificial disc of the present invention may have features or material characteristics to facilitate rigid attachment to bone. An artificial disc of the present invention may be adapted additional features known for attachment to bone including, but not limited to, spikes, screws, serration, and plate-like appendages generally exterior to the intervertebral disc space. Components may be made, in part, constructed of substantially porous materials for bone in-growth, yet have smooth non-porous regions for articulating surfaces. Surface treatments commonly practiced, such as beaded-coatings, may also be used for attachment to bone through eventual bone in-growth. In addition, within the scope of the current invention, components may be given flexibility through the use of geometry and materials to replicate the cushioning characteristics of the natural intervertebral disc. Additional components, such as, springs might be added to provide flexibility. In addition, portions of the patient's annulus may remain intact, such that the present invention augments a patient's existing intervertebral disc. Although the utility of the disclosed artificial disc is best achieved in the cervical region of the spine, adaptations for the thoracic and lumbar regions of the spine are also within the scope and spirit of the present invention.